

NOV - 8 2004

510(k) SUMMARY
Innoject Auto-injector**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:**

Innoject, Inc.
6136 FM 1616
Athens, TX 75752
Phone: (903) 677-5017
Facsimile: (903) 677-6083

Contact Person: Richard D. Gillespie III, P.E.

Date Prepared: September 15, 2004

Name of Device and Name/Address of Sponsor:

Trade Name:	Innoject Auto-injector
Name / Address of sponsor:	Innoject, Inc. 6136 FM 1616 Athens, TX 75752 Phone: 1-903-677-5017 Facsimile: 1-903-677-6083

Common or Usual Name: Auto Injector

Classification Name: Introducer, Syringe Needle
Regulation Number: 880.6920
Medical Specialty: General Hospital
Product Code: KZH
Device Class: Class II

Predicate Devices:

- Owen Mumford Inc.; *Autoject* Mini (K953735),
- Becton Dickinson; B-D Auto Injector (K974678),
- Scandinavian Health Ltd.; Pen-ject 2.25 (K954729),
- and
- Owen Mumford Inc.; *Autoject* 2 Model AJ 1330 Auto-injector (K945660)

Intended Use

The Innoject auto-injector is a semi-automatic injection system intended to be used for the manual transfer, containment and subcutaneous or intracavernosal injection of liquid drugs and biologics under the direction of a physician and according to approved drug or biologic labeling. The Innoject auto-injector system includes an automatic needle retraction mechanism that is intended to aid in the prevention of accidental needle sticks. The Innoject auto-injector system is intended to mask needle insertion, injection and needle withdrawal from patient view.

Technological Characteristics and Substantial Equivalence

The Innoject auto-injector consists of a syringe cartridge with prefixed needle, power pack housing with spring loaded mechanism to insert a hypodermic needle into a patient to predetermined depth below the skin surface and a window tube with spring-loaded retraction mechanism. It is button actuated, and once activated, the device automatically performs all three steps of the injection process, needle insertion, drug injection and needle withdrawal. The Innoject auto-injector is individually packaged and ETO sterilized for single use.

The Innoject auto-injector utilizes a spring-loaded mechanism to insert a hypodermic needle into a patient to predetermined depth below the skin surface and dispense the medication, and an automatic spring-loaded retraction mechanism. The same technological characteristics are found in various commercially marketed auto-injectors, which operate on the generally same principle.

In contrast to Innoject auto-injector, the predicate devices do not automatically retract the hypodermic needle after the injection process is completed.

The Innoject auto-injector is substantially equivalent to the other currently marketed auto injectors, which are referenced above. The Innoject auto-injector and its predicate devices are all Introducer, Syringe Needle products. As described in the substantial equivalency table and supported by the extensive testing performed by the company, the Innoject auto-injector raises no new issues of safety or effectiveness.

Performance Data

No performance standards have been established by FDA for this device. Dose accuracy, dead space, flow rate, injection time / dwell time, reliability (number of activations without failure), accuracy of penetration depth, needle bond strength, absence of leakage, verification of non-coring needle properties, needle penetration force, device actuation force, force necessary to defeat the button safety, force necessary to remove the cap, torque necessary to rotate the actuation button, verification of syringe markings accuracy, chemical resistance, free fall resistance, environmental stability were assessed. The device met all the requirements and specifications. In all instances, the Innoject auto-injector functioned as intended and the observed results were as expected.

Conclusion

Innoject, Inc. concludes based on the information presented herein that the Innoject auto-injector is substantially equivalent to similar products that have received FDA clearance and are currently legally marketed in the USA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 8 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innoject, Incorporated
C/O Mr. Jonathan S. Kahan
Partner
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004-5600

Re: K042557
Trade/Device Name: Innoject Auto-Injector
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: September 17, 2004
Received: September 20, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042557

Device Name: *Innoject* Auto-injector

Indications for Use:

The Innoject auto-injector is a semi-automatic injection system intended to be used for the manual transfer, containment and subcutaneous or intracavernosal injection of liquid drugs and biologics under the direction of a physician and according to approved drug or biologic labeling. The Innoject auto-injector system includes an automatic needle retraction mechanism that is intended to aid in the prevention of accidental needle sticks. The Innoject auto-injector system is intended to mask needle insertion, injection and needle withdrawal from patient view.

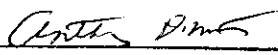
Prescription Use √
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042557